

CARRINGTON

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510(k) SUMMARY RADIACARE™ ORAL WOUND RINSE

1. **DATE PREPARED**

November 12, 1996

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2. **SUBMITTER**

Carrington Laboratories, Inc.
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Irving, TX 75038-4404

3. **CONTACT**

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4. **DEVICE NAME**

RadiaCare™ Oral Wound Rinse

5. **DEVICE CLASSIFICATION**

Surgical Wound Dressings have not been classified.
[Proposed Class I (CFR 878.4060)]

Product Code: 79 FRO

6. **DEVICE DESCRIPTION AND COMPARISON TO PREDICATE PRODUCTS**

RadiaCare™ Oral Wound Rinse is a wound dressing designed for the management of oral mucositis/stomatitis. The oral wound rinse is equivalent to the predicate device, Carrasyn® Oral Wound Dressing. Determination of substantial equivalence for this device was based on descriptive information about the design, materials and intended use of the device.

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The ingredients used in RadiaCare™ Oral Wound Rinse are the same as used in Carrasyn Oral Wound Dressing or are food-grade materials.

Two clinical trials have been conducted to date using Carrasyn Oral Wound Dressing. The first clinical trial was a randomized, double-blind, active-controlled study involved 60 healthy volunteer patients with at least one aphthous ulcer less than 48 hours duration. The patients were randomly assigned to two groups where one group of 30 patients were treated with Carrasyn Oral Wound Dressing and one group of 30 patients treated with a control. The patients were asked to apply the dressings topically four times per day and keep a diary as to the overall degree of discomfort and complete an adverse report form. Treatment was continued until the oral ulcers were healed. Carrasyn Oral Wound Dressing was found to reduce discomfort and no adverse events were reported in association with its use.

The second clinical study was an open-label, uncontrolled study involving 30 healthy volunteer patients with at least one aphthous ulcer less than 48 hours duration. All patients were treated Carrasyn Oral Wound Dressing. The patients were asked to apply the dressings topically four times per day and keep a diary as to the overall degree of discomfort and complete an adverse report form. Treatment was continued until the oral ulcers were healed. Carrasyn Oral Wound Dressing was found to significantly reduce discomfort within 2 minutes and no adverse events were reported in association with its use.

The above clinical studies demonstrate that Carrasyn Oral Wound Dressing is safe for oral use, relieves pain and has not been associated with any adverse events. It is also safe if swallowed. There were no safety concerns in either clinical study.

A pilot study used RadiaCare™ Oral Wound Rinse on two cancer patients with oral mucositis/stomatitis, a painful condition that results due to radiotherapy to the head and neck, and with some chemotherapeutic agents. Both reported relief of pain that lasted for approximately 2 hours.

Based on lack of any adverse events and on statistically and clinically significant reduction in discomfort associated with Carrasyn Oral Wound Dressing, this product is concluded to be a safe and effective agent in the management of oral mucositis/stomatitis and substantially equivalent to the predicate device, Carrington Wound Dressing.